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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,194	01/03/2005	Robert M Winslow	XSAN-1034867	3561

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,194	WINSLOW ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/22/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-5 are currently pending and are under examination.

Benefit of priority is to January 11, 2002.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabinovici et al. (1993; A new salutary resuscitative fluid: Liposome encapsulated hemoglobin/hypertonic saline solution. J. Trauma, 35(1): 121-127).

Rabinovici et al. teach liposome encapsulated hemoglobin in a hypertonic solution (see Table 1, Groups 2 and 3) comprising 7.5% NaCl. (see the first sentence of the abstract). They also teach hemoglobin in a hypertonic solution comprising hypertonic saline plus dextran qualitatively exerts the same responses as hypertonic saline (see page 127, right col., line 5+). Rabinovici et al. teach that liposome encapsulated hemoglobin has blood type and antigen free and has a remarkably stable shelf life (Abstract, line 7+). At page 5 of the specification, "modified hemoglobin" includes any hemoglobin having its structural or functional properties

altered from its native state. The specification at page 11 teaches that solutions comprising 7.5% NaCl or 7.5% NaCl in dextran have an osmolarity of between 800-2400 mOsm/l.

Therefore, Rabinovici et al. teach a blood substitute comprising modified hemoglobin (Claim 5), a crystalloid such as NaCl (Claims 3), in an aqueous diluent, wherein the osmolarity is greater than 800 mOsm/l and greater than 2000 mOsm/l (Claim 2).

Rabinovici et al. do not teach that the solution comprises less that 6 g/dl of hemoglobin. Rather, Rabinovici et al. teach that hemoglobin is 9.7 and 8.3 g/dl (Table 1, Groups 2 and 3). At page 12, para. 1 of the instant specification, the specification sets forth that the concentration of the oxygen carrier (hemoglobin) in the diluent may vary according to the application and in particular based on the expected post-administration dilution, and that it is usually unnecessary for the concentration (of hemoglobin) to be above 6 g/dl. It is also noted that in Example 1 at pages 12-13, the concentration of PEG-modified hemoglobin administered to SD rats is not disclosed. It is noted that Rabinovici et al. also administered the liposome encapsulated hemoglobin in hypertonic saline to SD rats.

Therefore, it appears that the blood substitute claimed and the blood substituted taught in Rabinovici et al. are functionally the same, and whether the hemoglobin concentration is less than 6 g/dl or greater than 6 g/dl at about 9 g/dl does not affect the ability of either blood substitute to reverse hypovolumia. As noted above, the teachings of the specification supports this conclusion. Therefore, the claimed blood substitute is considered to be an obvious variation of the blood substitute taught by Rabinovici et al.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rabinovici et al. (1993; A new salutary resuscitative fluid: Liposome encapsulated hemoglobin/hypertonic saline solution. J. Trauma, 35(1): 121-127) as applied to claim1 above, and further in view of Shorr et al. (USP 5,312,808).

The teachings of Rabinovici et al. are set forth above. Rabinovici et al. do not teach blood substituted comprising polyalkylene oxide conjugated hemoglobin.

Shorr et al. teach polyalkylene oxide conjugated hemoglobin. Shorr et al. teach that polyalkylene oxide conjugated hemoglobin is advantageous over other hemoglobin compositions because it overcomes the hemoglobinuria problems associated with other hemoglobin compositions (Col. 3, line 38-41, Example 5 at Col. 11).

It would have been obvious to a person having ordinary skill in the art to substitute the polyalkylene oxide conjugated hemoglobin of Shorr et al. for the liposome encapsulated hemoglobin of Rabinovici et al. because Shorr et al. teaches that polyalkylene oxide conjugated hemoglobin overcomes the hemoglobinuria problems associated with other hemoglobin compositions.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER